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U S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

DATE: March 3, 2000

EXPRESS MAIL LABEL NO.
EM341130105USATTORNEY DOCKET NO.
37187/DBPU.S. APPLICATION NO.
To Be Assigned

09/508045

**TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371**

INTERNATIONAL APPLICATION NO PCT/DE98/02695	INTERNATIONAL FILING DATE 4.September.1998	PRIORITY DATE CLAIMED 4.September.1997
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TITLE OF INVENTION
ELECTRODE ARRANGEMENT FOR ELECTROTHERMAL TREATMENT OF HUMAN OR ANIMAL BODIES

APPLICANT(S) FOR DO/EO/US

Gerhard Muller; Kai Desinger; and Thomas Stein

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. This is an express request to begin national examination procedures (35 U.S.C. 371(f) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. A copy of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. is transmitted herewith (required only if not transmitted by the International Bureau)
 - b. has been transmitted by the International Bureau.
 - c. is not required, as the application was filed in the United States Receiving Office (RO/LUS).
6. A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. have been transmitted by the International Bureau.
 - c. have not been made; however, the time limit for making such amendments has NOT expired.
 - d. have not been made and will not be made.
8. A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items below concern other document(s) or other information included:

11. An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. A **FIRST** preliminary amendment.
 - a. A **SECOND** or **SUBSEQUENT** preliminary amendment.
14. A substitute specification.
15. A change of power of attorney and/or address letter.
16. Small entity claim with a copy of this transmittal letter attached. (TO FOLLOW)
17. International search report.
18. International preliminary examination report.
19. Extra set of drawings
20. English Translation of the International Application with Annexes to IPER Incorporated
21.

428 Recd PCT/PTO 03 MAR 2000

U.S. APPLICATION NO. (If known, see 37 CFR 1.1)	INTERNATIONAL APPLICATION NO.	ATTORNEY DOCKET NO.		
To Be Assigned 09/508045	PCT/DE98/02695	37187/DBP		
<input checked="" type="checkbox"/> The following fees are submitted: (see Note (1) below) Basic National Fee (37 CFR 1.492(a)(1)-5): Search Report has been prepared by the EPO or JPO \$ 840.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) ... \$ 670.00 No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)) \$ 690.00 Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$ 970.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4).... \$ 96.00		CALCULATIONS	PTO USE ONLY	
ENTER APPROPRIATE BASIC FEE AMOUNT =		\$ 840.00		
Surcharge of \$130 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).		\$		
Claims	Number Filed	Number Extra	Rate	
Total Claims	13 ⁺⁵ -20=	0	X \$18	\$ 0.00
Independent Claims	1 -3=	0	X \$78	\$ 0.00
Multiple dependent claim(s) (if applicable)		+ \$260	\$ 260.00	
TOTAL OF ABOVE CALCULATIONS =		\$ 1,100.00		
Reduction by 1/2 for filing by small entity, if applicable. Verified Small entity statement must also be filed. (Note 37 CFR 1.9, 1.27, 1.28).		\$		
SUBTOTAL =		\$ 1,100.00		
Processing fee of \$130 for furnishing the English translation later than <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).		\$		
TOTAL NATIONAL FEE =		\$ 1,100.00		
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property		\$		
TOTAL FEES ENCLOSED =		\$ 1,100.00		
Note (1): The basic national fee must be paid when filing this application. The 20-month time limit (37 CFR § 1.494) and 30-month time limit (37 CFR § 1.495) are not extendable.		Amount to be: refunded \$ charged \$		
a. <input checked="" type="checkbox"/> A check in the amount of <u>\$ 1,100.00</u> to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of _____ to cover the above fees A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>03-1728</u> . A duplicate copy of this sheet is enclosed.				
NOTE (2): Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.				
SEND ALL CORRESPONDENCE TO:				
D. Bruce Prout CHRISTIE, PARKER & HALE P.O. Box 7068 Pasadena, CA 91109-7068		By <u>D. Bruce Prout</u> D. Bruce Prout Reg. No. 20,958		

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

This paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" under 37 CFR § 1.10, Mailing Label No. EM341130105US.

Applicant : Gerhard Muller, et al.
Application No. : To Be Assigned
Filed : Herewith
Title : ELECTRODE ARRANGEMENT FOR
ELECTROTHERMAL TREATMENT OF
HUMAN OR ANIMAL BODIES
Grp./Div. : To Be Determined
Examiner : To Be Determined
Docket No. : 37187/DBP/E43

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Post Office Box 7068
Pasadena, CA 91109-7068
March 3, 2000

Commissioner:

Please amend the above-identified application as follows:

IN THE CLAIMS:

Please delete Claims 1 through 13 and insert in their place the following claims:

- 1 --14. An electrosurgery apparatus comprising an electrode carrier (31, 61a-c) at least one electrode (32,
2 33, 62, 63) on the electrode carrier, an alternating current source (81) conductively connected to the electrode
3 by way of a cable, and a temperature control device (35, 64, 65, 84) for the electrode and the electrode
4 carrier, wherein the electrode carrier is of a pointed configuration at its distal end, characterised in that there
5 are provided means (85) by way of which the electrode or electrodes and the electrode carrier are heatable
6 independently of the amplitude of the alternating current flowing through the electrode or electrodes.--

- 1 --15. An electrosurgery apparatus as set forth in claim 1 characterised in that the electrode or electrodes
2 (32, 33, 62, 63) and the electrode carrier (31, 61a-c) are heatable to a temperature of more than 30 degrees.--

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1 --16. An electrosurgery apparatus as set forth in claim 2 characterised in that the electrode or electrodes
2 (32, 33, 62, 63) and the electrode carrier (31, 61a-c) are heatable to a temperature of more than 37 degrees.--

1 -17. An electrosurgery apparatus as set forth in any one of the preceding claims characterised in that the
2 electrode or electrodes (62, 63) and/or the electrode carrier (61a, 61b) have a cavity (64, 65) and that the
3 temperature control device includes a temperature-controllable fluid source (83, 85) which is in
4 communication with the electrode (62, 63) and/or the electrode carrier (61a, 61b) by way of a quantitative
5 flow control device (84,87). --

1 -18. An electrosurgery apparatus as set forth in one of claims 14 through 16 characterised in that the
2 electrode (32, 33, 62, 63) and/or the electrode carrier (31, 61a-c) has a thermoelectric heating and cooling
3 device. --

1 -19. An electrosurgery apparatus as set forth in claim 14, characterised in that there is provided an
2 effective temperature profile control device (87) which is connected by way of a control signal connection
3 to the temperature control device (83).--

1 -20. An electrosurgery apparatus as set forth in claim 19 characterised in that the effective temperature
2 profile control device (87) for controlling the alternating current power is connected by way of a control
3 input to the alternating current source (81).--

1 -21. An electrosurgery apparatus as set forth in claim 19 or claim 20 characterised in that the effective
2 temperature profile control device (87) includes an interactively programmable calculation unit (87.2) for
3 determining simulated, time-dependent effective temperature profiles on the basis of parameters of the tissue
4 and the electrode (82) and assumed parameters of the alternating current source (81) and the temperature
5 control device (83), and for varying the assumed parameters to ascertain an optimized, time-dependent
6 effective temperature profile.--

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1 -22 An electrosurgery apparatus as set forth in claims 19, characterised by at least one low-inertia
2 temperature sensor (86) which is connected to an input of the effective temperature profile control device
3 (87) and which can be arranged in the body adjacent to the electrode (32, 33, 62, 63) or the electrode carrier
4 (31, 61a-c).--

1 -23. An electrosurgery apparatus as set forth in claim 22 characterised in that the temperature sensor (86)
2 is connected to an input of the calculation unit (87.2) and that the calculation unit (87.2) has means for
3 verification or correction of a simulated, time-dependent effective temperature profile on the basis of the
4 measurement signal of the temperature sensor. --

1 -24. An electrosurgery apparatus as set forth in claim 14 characterised in that the effective temperature
2 profile control device has means (87.1, 87.2, 87.6) for storing and calling up the time-dependency of control
3 signals and for outputting control signals in accordance with a stored time-dependency.--

1 -25. An electrosurgery apparatus as set forth in claim 14 characterised in that the electrode carrier (31,
2 61a-c) has a tubular element (61a, 61b) of electrically insulating material with a decreasing, in particular
3 conical distal end, on the peripheral surface of which is arranged the electrode (62, 63) and in the interior
4 of which is arranged the temperature control device (64, 65).--

1 -26. An electrosurgery apparatus as set forth in claim 14, characterised by two electrodes (32, 33; 62, 63)
2 on the electrode carrier (31; 61a, 61b).--

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REMARKS

In view of the foregoing amendments, consideration and allowance of this application is respectfully requested.

Respectfully submitted,

CHRISTIE, PARKER & HALE, LLP

By D. Bruce Prout
D. Bruce Prout
Reg. No. 20,958
626/795-9900

DBP/sfc

SFC PAS236319.1--*-3/3/00 6:07 PM

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37187/DBP/E43

**English Translation of International Application
with Annexes to International Preliminary
Examination Report Incorporated**

09/508045
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IN THE UNITED STATES PATENT AND TRADE MARK OFFICE

VERIFICATION OF TRANSLATION

I, Michael Wallace Richard Turner, Bachelor of Arts, Chartered Patent Attorney, European Patent Attorney, of 1 Horsefair Mews, Romsey, Hampshire SO51 8JG, England, do hereby declare that I am conversant with the English and German languages and that I am a competent translator thereof;

I verify that the attached English translation is a true and correct translation made by me of the attached documents in the German language of International Application PCT/DE98/02695;

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: February 29, 2000

M W R Turner

M W R Turner

121 P228.

WO 99/11186

PCT/DE98/02695

Electrode arrangement for electrothermal treatment of the human or
animal body

Description

The invention concerns an electrode arrangement for electrothermal treatment of the human or animal body, in particular for electrocoagulation, as set forth in the classifying portion of claim 1.

- 5 The application of high-frequency alternating currents (specifically in the frequency range of between 300 kHz and 2 MHz) to generate high temperatures for tissue coagulation as a surgical procedure has long been known. In practice monopolar or bipolar electrode arrangements are used for introducing the HF-current into the tissue.
- 10 In the case of the monopolar arrangements, an electrode - also referred to as the neutral electrode - is designed in the form of a patient delivery line of large area and fixed to the patient not too far away from the point of intervention and earthed or connected to ground. A second electrode which is manipulated by the operator - also referred to as the active electrode - is connected to the alternating current generator. In terms of its shape, that electrode is selected to be adapted to the respective use involved, in particular the size of the tissue region to be treated, in such a way that both the operational time and also the thermal loading of the region of the body or organ involved are reasonable.
- 15

In the case of arrangements for bipolar HF-surgery, both electrodes are connected to the HF-generator and are of mutually comparable dimensions, and are placed by the operator in the immediate proximity of the intervention location and are generally also both guided actively.

- 5 Bipolar electrode arrangements are also known in which both coagulation electrodes are arranged on a catheter.

WO 97/17009 discloses a bipolar electrode arrangement with a fluid duct, by way of which flushing fluid can be introduced into the operational area.

- 10 WO 96/34569 and the documents referred to in the international search report disclose systems and processes for the ablation of body tissue while maintaining a pre-calculated maximum tissue temperature, in which fluid cooling or thermoelectric cooling is provided during the actual tissue coagulation procedure. Those known arrangements are intended
15 for the introduction into body cavities by way of natural accesses.

The object of the invention is to provide an electrode arrangement of the kind set forth in the opening part of this specification, which permits quick and easy interstitial tissue coagulation even in relatively treatment regions.

- 20 Taking an electrode arrangement as set forth in the classifying portion of claim 1, that object is attained by the features recited in the characterising portion of claim 1.

The invention includes the basic teaching that the electrode arrangement is mechanically designed in such a way as to facilitate direct
25 penetration into body tissue and at the same time there are provided thermal means for setting an advantageous effective temperature profile for the insertion phase.

- That notion is based on the fact that the known arrangements which are cooled during the actual electrotherapy procedure have
30 admittedly afforded many advantages, but they are not well suited to being inserted into body tissue directly (invasively), with duct formation,

for interstitial use. For that reason, in clinical practice, in many cases a duct to the treatment region is firstly opened with a separate incision instrument and in an additional working step on the part of the operator, before the electrothermy applicator is advanced in the duct.

5 It is further based on the realization on the part of the inventors that a "cold" applicator can be inserted with more difficulty than one which has been warmed somewhat.

A short-term temperature control procedure to a temperature above about 30°C, more especially somewhat above body temperature,
10 has proven to be advantageous for the insertion phase. As soon as the applicator has reached the treatment location and the actual electrothermal treatment is initiated, the procedure involves implementing a transition to adjusting an effective temperature profile which is optimized in regard to optimum coagulation performance. Even in periods
15 of time of that phase, heating in addition to the generation of heat by way of the electrodes can be desirable.

In a particularly effective and at the same time inexpensive embodiment the electrode or electrodes or the electrode carrier are provided with a cavity which is closed off in relation to the body and which
20 is connected to a fluid source which can be the subject of temperature control within a predetermined range so that the suitably temperature-controlled fluid flows through the electrode or the carrier thereof.

Preferably distilled water is used as the fluid, having regard to the low costs involved and the simple and safe handling thereof. In addition
25 for specific situations of use - possibly having regard to specific safety precautions - it is also possible to use other fluids which have proven their worth as heat-transfer agents, for example compressed air, carbon dioxide or silicone oil.

In another possible embodiment the electrode or the electrode
30 carrier has a thermoelectric heating and cooling device which can be for

example in the form of a combination of resistance heaters and Peltier elements.

In an embodiment which is simple to produce and handle, the electrode carrier is a tubular, in particular cylindrical element of electrically

- 5 insulating material, on the peripheral surface of which is or are arranged one or more electrodes and in the interior of which is arranged the temperature control device. To facilitate penetration into the tissue, the electrode carrier desirably has a distal end which decreases or tapers to an approximately conical tip, and the electrodes are fitted substantially
- 10 flush into the peripheral surface of the carrier.

In the preferred embodiment in the form of a bipolar arrangement, the assembly includes two electrodes which are mounted to one and the same electrode carrier, in particular in an axial row. In that case, a common temperature control device is provided for both electrodes, for

- 15 example the above-mentioned internal tube counterflow temperature control device.

In the preferred embodiment of this alternative configuration, the carrier element is of a cylindrical cross-section, while the two electrodes are of a hollow-cylindrical design and are arranged coaxially with respect

- 20 to the longitudinal axis of the carrier element. For that purpose the electrodes can be disposed for example in the form of a metallic coating on the surface of the carrier element or each comprise a metal sleeve (for example of titanium or Nitinol) which is pushed onto the carrier element or better inserted flush and forms therewith a press fit.

- 25 In a particularly simple embodiment of this arrangement, which is safe and secure in terms of handling, axial fixing of the electrodes is not effected by a continuous carrier element, but by a hollow connecting element which connects the electrodes (which are also hollow) together at their ends. Besides axial fixing of the electrodes, the connecting element
- 30 also performs the function of insulating the two electrodes relative to each other and it therefore comprises an electrically insulating material,

preferably PEEK (polyetheretherketone). The electrodes, the connecting portion and the supply line for the cooling agent (for example a relatively stiff PTFE-hose which at the same times serves as a handle or gripping portion) are preferably annular or tubular and are of the same cross-section so that the surface of the catheter is a closed cylindrical configuration, whereby insertion into the body is facilitated and at the same time unwanted current density peaks can be substantially avoided.

In an alternative configuration of the preferred bipolar arrangement which can be used in a particularly variable fashion but which is more expensive in regard to structure, the axial spacing between the two electrodes is adjustable in order to be able to additionally vary the current density distribution and thus the heating output distribution. If the insulator length between the two electrodes in the axial direction is for example less than double the electrode diameter, it is advantageously possible to produce spherical coagulation necroses whereas the shape of the coagulation necroses with greater insulator lengths is rather oval.

The geometrical configuration of tissue coagulation can be substantially influenced by the temperature control effect - specifically by the choice of heating/cooling in a given sequence in respect of time.

In a preferred embodiment, besides the electrode or electrodes and the actual cooling device, an electrosurgery apparatus which makes use of the invention includes control means for establishing an advantageous effective temperature profile in the treatment region. The control means include in particular an effective temperature profile control device for controlling the heating or cooling output and/or the spatial distribution thereof, said control device being connected to the cooling device by way of a control signal connection for supplying a heating and/or cooling output control signal.

The effective temperature profile control device can also be adapted to produce and supply a heating output control signal for controlling the alternating current power and/or the spatial distribution thereof, and can

be connected to the alternating current source by way of a control input so that, besides the cooling device, it can also control the HF-source - acting as a "heating device" in the tissue. That provides for particularly flexible control of the treatment regime in the event of longer-duration

5 intervention procedures.

The effective temperature profile control device preferably includes an interactively programmable calculation unit for determining simulated time-dependent effective temperature profiles on the basis of parameters of the tissue and the electrode arrangement and assumed parameters of

10 the alternating current source and the heating or cooling device and for effecting a variation in the assumed parameters to ascertain an optimized effective temperature profile. In practice, use will be made of a PC with which the spatial temperature distribution and optionally the time-dependency thereof can be determined and on the screen of which the

15 simulated effective temperature profiles can be represented as an image. That already makes it considerably easier for the operator, prior to an intervention procedure, to select a suitable combination of control values of the temperature control device and the HF-source.

Placing at least one temperature sensor which responds with a low

20 level of inertia and which is connected to an input of the effective temperature profile control device at a predetermined position relative to the electrode arrangement in the body, in particular at an electrode or the electrode carrier, makes it possible to implement verification or rescaling of a simulated effective temperature profile during the intervention. The

25 parameters which are to be used in the further course of the treatment can therefore be freshly adjusted at any moment in time.

Additional possible options in that respect are afforded by the provision of a device for ascertaining (especially in time-dependent fashion) the heating or cooling output produced by the temperature

30 control device or a value influencing the heating or cooling output, and a

device for ascertaining the alternating current power outputted by the alternating current source, or a value influencing such current power.

Insofar as the effective temperature profile control device preferably has means for determining and storing a time-dependency of 5 the cooling output control signal and/or the heating output control signal and for outputting the respective control signal in accordance with the stored time-dependency, a treatment which is established in advance in terms of the operations to be performed by the operator can take place substantially automatically, in regard to the control values. It will be 10 appreciated in that respect that current changes in the control values still remain possible so that the operator can also react flexibly to unforeseen events. As changes of that kind can be detected and can be incorporated into an updated simulation calculation, the consequences for further progress of the intervention procedure can in turn be made clear to the 15 doctor in a virtually real-time mode.

Advantageous developments of the invention are moreover characterised in the appendant claims or are set forth in greater detail hereinafter together with the description of the preferred embodiment of the invention with reference to the Figures in which:

20 Figure 1 is a graph view of a current density distribution, obtained as the result of a simulation calculation, along a bipolar electrode arrangement with two axially mutually displaced annular electrodes in body tissue,

25 Figure 2 is a diagrammatic view of the tissue conditions which are formed around an electrode arrangement shown in Figure 1 without temperature control,

Figures 3 is a diagrammatic view of the tissue conditions which are formed around an electrode arrangement shown in Figure 1 with temperature-controlled electrodes,

30 Figure 4 shows a comparative graph view of the temperature variation in the region of a non-temperature-controlled and a

temperature-controlled electrode arrangement in dependence on the spacing from the electrode surface,

Figures 5a and 5b show comparative views of the time-dependency of the tissue impedance measured in the course of a coagulation treatment and the electrical power outputted to the tissue in the case of a non-temperature-controlled and a temperature-controlled electrode arrangement,

Figures 6a and 6b are diagrammatic view in longitudinal section of a bipolar electrode arrangement with two axially mutually displaced fixed annular electrodes and internal fluid temperature control in accordance with an embodiment of the invention,

Figure 7 is a diagrammatic view of a bipolar electrode arrangement with mutually displaceable electrodes and internal temperature control in accordance with a further embodiment of the invention,

Figure 8 is a diagrammatic view showing the principle of an electrosurgery apparatus with measuring arrangement for determining essential treatment values,

Figure 9 shows a structure chart of a simulation program for on-line dosimetry in interstitial HF-thermotherapy,

Figure 10 is a pictorial representation of a simulation event, and

Figure 11 shows a block circuit diagram of the effective temperature profile control device of the electrosurgery apparatus shown in Figure 8.

Figure 1 is a diagrammatic view in longitudinal section of a current density distribution obtained as the outcome of a simulation calculation by the inventors, along a bipolar electrode arrangement 10 with a pointed electrode 12 and an annular electrode 13 fixed axially at a spacing relative to the tip electrode 12 by an insulating electrode carrier 11 and insulated with respect to the tip electrode 12 in the body tissue 14. The portion of the electrode arrangement 10 in proximal relationship to the annular electrode 13 is surrounded by an insulating casing 15. Besides the view in longitudinal section, the Figure also lists in table form the maximum

current density (max) and the current density stages a through q which form the basis involved in representing the stimulation result.

It can already be seen at the few current density areas which can be seen at all in the longitudinal section, from the Table (essentially only 5 the areas represented by the lines a through g), that current density peaks occur at the tip and in each of the boundary regions of the electrodes 12, 13 in relation to the insulating portions 11, 15 of the arrangement and the current density overall already falls severely at a small spacing from the surfaces. This shows that it is to be assumed that 10 by far the greatest part of the electrical energy which is introduced into the body tissue 14 by the electrode arrangement 10 is converted into thermal energy in the tissue regions immediately adjoining the electrode surfaces. Tissue coagulation begins in the zones of highest current density at the mutually facing electrode edges.

15 As is diagrammatically shown in Figure 2, that results in the formation of a drying-out zone approximately in the configuration of a narrow rotational ellipsoid around an electrode arrangement of that kind. The electrode arrangement 20 shown in Figure 2 - in a slightly modified form in comparison with the configuration shown in Figure 1 - includes two 20 cylindrical electrodes 22, 23 of equal length which are let into a cylindrical carrier 21, while the tip 20a is here of an insulating nature. The surrounding tissue 24 is divided in dependence on the temperature and the changes in tissue produced thereby into the drying-out zone 24A, a coagulation zone 24B and a structurally unchanged ("native") outer region 24c. In addition, particularly with a high level of power being introduced, 25 a carbonization layer or zone (not shown in the Figure) can be formed directly at the surface of the arrangement.

The formation of the drying-out zone 24A dramatically worsens the electrical properties of the treatment region, in regard to an 30 electrosurgical treatment. The increase in impedance as a result of the disappearance of tissue fluid results in a considerable reduction in the level

of electrical energy which is coupled into that zone and thus overall into the tissue 24. In addition a carbonization zone represents a region of low thermal conductivity and additionally worsens the treatment efficiency.

That was confirmed by measurements taken by the inventors, as

- 5 Figure 5a shows. This Figure is a representation of the time-dependency of the tissue impedance measured in the course of a coagulation treatment, and the electrical power outputted to the tissue, in an electrode arrangement which does not involve temperature control. It can be seen from the Figure that, after an initial fall which is thought to be
10 attributed to the agglomeration or accumulation of tissue fluid at the electrode surface, the impedance is almost constant at a value of around 100 Ω over a certain treatment duration. That permits an energy input of about 9 W (in the case of the arrangement which is here set to a maximum power of 10 W). After a treatment duration of about 6 minutes
15 however the impedance suddenly jumps to about four times, as a result of drying-out of the electrode-tissue interface, and that results in a reduction in the electrical power converted to 2-3 W.

Figure 3 diagrammatically shows how the provision of internal temperature control for the electrode arrangement acts on the tissue

- 20 conditions which are formed in the treatment region. The electrode arrangement 30 diagrammatically shown in Figure 3 includes - in this respect being in conformity with the structure shown in Figure 2 - two cylindrical electrodes 32, 33 of equal length which are let into a cylindrical carrier 31 and an insulating tip 30a. Reference 35 and the arrows at the
25 proximal end of the illustrated part of the arrangement diagrammatically indicate a fluid counter-flow temperature control effect. The surrounding tissue 34 is divided into a relatively cool zone 34A, a coagulation zone 34B and a structurally unchanged outer region 34C. The formation of a carbonization layer is either not observed at all with such an arrangement,
30 or at any event it does not begin directly at the electrode surface.

The conditions diagrammatically shown in Figure 3 can also be seen from a comparative graph representation of the spatial variation in temperature in the region of a non-temperature-controlled and a temperature-controlled electrode arrangement, as is shown in the upper 5 region of Figure 4. The lower part of that Figure represents a sketch to illustrate the values which are linked in the function curves and also the external shape of the electrode arrangement.

It can be clearly seen from the function curves $T(r)$ - which show the conditions at a moment in time shortly after beginning to apply the ac 10 voltage - that the coagulation zone enlarges by a radius difference value Δr , in the case of a temperature-controlled arrangement. That already demonstrates the higher level of efficiency of the cooled arrangement. It is to be noted in regard to the function curve for the temperature-controlled arrangement that - depending on the respective setting of the 15 temperature of the temperature control fluid - in practice the coagulation temperature is also exceeded in the electrode interface region after a certain period of treatment, so that treatment success also occurs in that region.

Figure 5b shows the time-dependency of the tissue impedance and 20 the electrical power outputted to the tissue, when using a temperature-controlled electrode arrangement. It will be seen that the impedance (once again after an initial fall) and the converter power remain practically constant over the treatment period.

Figures 6a and 6b are a partly sectional view and a view in 25 longitudinal section (in different sectional planes) of a temperature-controlled bipolar electrode arrangement 60 as an applicator for HF-induced interstitial thermotherapy of pathological tissue. It includes a tubular plastic carrier 61a, two axially mutually displaced, fixed metal annular electrodes 62, 63 which are fixed and insulated relative to each 30 other by way of an annular plastic intermediate carrier 61b, a plastic tip 61c, an inner tube 64 and an inner tube spacer 64a. The electrodes are

connected to an HF-generator by way of lines (not shown in the Figure) comprising highly flexible stranded copper wires.

Depending on the area of use involved, the electrodes 62, 63 are of a diameter in the region of between 1 and 5 mm and are of a length of
5 between 2 and 30 mm. In the illustrated example they are in the form of NITINOL-tubes and are pushed onto the plastic members 61a, 61b and 61c made from high temperature-resistant PEEK (polyethyletherketone) and glued in position thereon by means of high temperature-resistant adhesive. The diameter of the plastic members is adapted to that of the
10 electrodes; the length of the intermediate portion is between 1.5 and 3 times the electrode diameter. The electrode regions which are disposed on the plastic members are coated with PTFE. The inner tube 64 comprises PTFE. Instead of the materials specified, it is also possible to use other tried-and-tested biocompatible materials which are easily
15 slidable into body tissue and which are sufficiently temperature-resistant.

In order to guarantee easy duct-forming insertion directly into body tissue, besides the applicator being of a suitable configuration, the use of polished electrodes and possibly a slip or anti-friction coating are of advantage.

20 The electrode arrangement 60 is operated with an HF-power of up to 100 W (in the treatment of liver metastases or benign prostate hyperplasia for example 50-60 W). The temperature control medium introduced into the inner tube 64 is sterile distilled water at a temperature which is adjustable in dependence on time in the range of between 0 and
25 80°C (for example upon introduction and at the beginning of the electrotherapy treatment above 30°C and then ambient temperature) under a pressure of between 0 and 3 bars (for example 1 bar) at a flow rate of up to 200 ml/min (in the above-indicated example 40-60 ml/min). The water flows through the inner tube to the distal end thereof in the
30 region of the tip 61c, it there passes into the annular space 65 between

the inner tube and the outer wall of the arrangement and it flows back in the annular space to the exterior of the body where it is drained away.

Finally Figure 7 is a diagrammatic view of a further electrode catheter 70 which permits adjustment of the electrode spacing in order to
5 be able to influence the field and current density distribution in the therapy area. For that purpose the catheter 70 has a cylindrical carrier element 71 of electrically insulating material, in the proximity of the distal end of which is disposed a first electrode 72, in the form of an annular metal coating. In its insulating region the carrier element 71 is axially
10 displaceably guided by a second electrode 73 which extends around it and which is of a hollow-cylindrical configuration, in order to be able to adjust the electrode spacing and thus to make available an additional optional way of varying the effective temperature profile in the treatment region.

Figure 8 is a diagrammatic view showing the principle of an
15 electrosurgery apparatus 80 with an HF-generator 81, an electrode catheter 82 (also referred to as an "HF-needle"), a temperature control fluid container 83, a temperature control fluid pump 84 and a temperature control fluid heater 85, as well as a measuring and evaluation arrangement for establishing essential treatment values. The measuring and evaluation arrangement here includes a storage oscilloscope 86 for
20 detecting the electrical values, a quantitative flow meter 89 for detecting the temperature control fluid flow rate, a T-sensor 88 arranged in the treatment region, and a PC 87 connected by way of a suitable measurement data interface to the measuring devices 86, 88 and 89, for
25 evaluation of the measurement values.

By virtue of the choice of suitable control members, for example a controllable HF-generator 81, a controllable fluid pump 84 and a controllable fluid heater 85 which are connected by control lines (shown in dash-dotted line in the Figure) to the PC 87 (or a separate control unit
30 connected to the PC), this arrangement can be used to control the essential treatment values, HF-output power and heating or cooling

output, in the course of an electrosurgical intervention, on the basis of active power measurement and impedance measurement and/or temperature measurement in the treatment space.

In particular, for the insertion phase, the fluid temperature and

- 5 therewith (HF-generator 80 switched off) the temperature of the HF-needle 81 can be raised by means of the fluid heater 85 to a value in the region of body temperature or above. In this phase the fluid pump 84 can be operated with a relatively low delivery or intermittently and a T-regulation action can possibly be omitted. After positioning of the HF-
- 10 needle and when the HF-generator is switched on - or even better with a time delay after it is switched on, such time delay being predetermined or derived from signals from the T-sensor - the fluid heater is switched off. In that phase, in the normal situation, the fluid pump is controlled on the basis of the predetermined target temperature field or range and with
- 15 evaluation of the signals from the T-sensor, so that T-regulation then takes place. However differentiated actuation of the fluid pump and the fluid heater can also be implemented throughout the entire interventional procedure on the basis of a predetermined time-dependent target temperature field or range which takes account of the particular requirements of the insertion phase.

The methodological basis of a representation of therapy progress is a simulation calculation which is based on the method of finite differences to solve the differential equations which describe the electrical and thermal phenomena involved. The fundamental procedure is

- 25 diagrammatically shown in Figure 9 which does not require any further commentary.

Figure 10 is a pictorial representation of a simulation result as it appears on a computer screen. Illustrated therein are the T-distribution and the limits or boundaries of the treatment region ("Damaged") around

- 30 an applicator which, on an insulating carrier body 101, carries two electrodes 102 and 103 arranged axially in a row.

Figure 11 shows a function block circuit diagram of an embodiment of the integrated evaluation and control device 87 of the HF-applicator system 80 from Figure 8. The peripheral components are illustrated in Figure 8 and are therefore omitted from Figure 11, and also the foregoing 5 description relating to the fundamental control functions is not repeated here in relation to Figure 11.

The evaluation and control device 87 includes as its main components a procedure control (controller) 87.1, an effective temperature profile calculation unit 87.2 and a control value calculation 10 unit 87.3. Associated with those components in the usual manner are separate program and data stores 87.2a, 87.2b and 87.3a, 87.3b respectively and jointly an I/O-interface 87.4, an input unit 87.5 and a display unit 87.6. The control value calculation unit 87.3 additionally has associated therewith at its output side a control procedure store 87.6 for 15 storage of calculated time-dependencies of the cooling and heating output control signal whose access control (not shown separately) is connected to the controller 87.1.

The program and the data stores 87.2a, 87.2b of the effective temperature profile calculation unit 87.2 store in particular the above-mentioned simulation program ("dosimetry program") and the data sets which are required for implementation and which can be updated by current inputs by way of the input unit 87.5 on the part of the operator and automatically upon the input of new measurement data, by way of the interface 87.4. Accordingly, in each phase of a treatment - including the 20 duct-forming insertion of the HF-needle - it is possible to acquire a current stimulation result for the effective temperature profile (see Figure 10) and thus a prognosis about further progress in the treatment.

The program and the data stores 87.3a, 87.3b of the control value calculation unit 87.3 store in particular algorithms and parameter sets 30 which permit an association of specific control data sets with effective temperature profile data sets, possibly also control data tables which are

already directly accessible. Complete control data sets for an overall treatment can be advanced into the control procedure store 87.6 after the conclusion of a preparatory or updated simulation calculation, from where they can be outputted by way of the controller 87.1 to the automatic

5 timing control in respect of the treatment parameters for adjustment of the fluid pump 84, the fluid heater 85 and the HF-generator 81 (Figure 8). In this respect also a corrective intervention on the part of the operator is possible in any phase.

The invention is no limited in terms of its implementation to the
10 preferred embodiments set forth hereinbefore. On the contrary it is possible to envisage a number of alternative configurations which also make use of the claimed solution, in configurations of different kinds.

Berlin 19th August 1999
Our reference: LB8613
Applicants/proprietors: Laser- und Medizin-Technologie gGmbH, Berlin,
et al.
Filing No: PCT/DE 98/02695

New claims

1. An electrosurgery apparatus comprising an electrode carrier (31, 61a-c) at least one electrode (32, 33, 62, 63) on the electrode carrier, an alternating current source (81) conductively connected to the electrode by way of a cable, and a temperature control device (35, 64, 65, 84) for the electrode and the electrode carrier, wherein the electrode carrier is of a pointed configuration at its distal end, characterised in that there are provided means (85) by way of which the electrode and the electrode carrier are heatable independently of the electrical current strength through the electrode.
2. An electrosurgery apparatus as set forth in claim 1 characterised in that the electrode (32, 33, 62, 63) and the electrode carrier (31, 61a-c) are heatable to a temperature of more than 30 degrees.
3. An electrosurgery apparatus as set forth in claim 2 characterised in that the electrode (32, 33, 62, 63) and the electrode carrier (31, 61a-c) are heatable to a temperature of more than 37 degrees.

4. An electrosurgery apparatus as set forth in one of the preceding claims characterised in that the electrode (62, 63) and/or the electrode carrier (61a, 61b) has a cavity (64, 65) and that the temperature control device includes a temperature-controllable fluid source (83, 85) which is in communication with the electrode (62, 63) and/or the electrode carrier (61a, 61b) by way of a quantitative flow control device (84,87).

5. An electrosurgery apparatus as set forth in one of claims 1 through 3 characterised in that the electrode (32, 33, 62, 63) and/or the electrode carrier (31, 61a-c) has a thermoelectric heating and cooling device.

6. An electrosurgery apparatus as set forth in one of the preceding claims characterised in that there is provided an effective temperature profile control device (87) which is connected by way of a control signal connection to the temperature control device (83).

7. An electrosurgery apparatus as set forth in claim 6 characterised in that the effective temperature profile control device (87) for controlling the alternating current power is connected by way of a control input to the alternating current source (81).

8. An electrosurgery apparatus as set forth in claim 6 or claim 7 characterised in that the effective temperature profile control device (87) includes an interactively programmable calculation unit (87.2) for determining simulated, time-dependent effective temperature profiles on the basis of parameters of the tissue and the electrode (82) and assumed parameters of the alternating current source (81) and the temperature control device (83), and for varying the assumed parameters to ascertain an optimized, time-dependent effective temperature profile.

9. An electrosurgery apparatus as set forth in one of claims 6 through 8 characterised by at least one low-inertia temperature sensor (86) which is connected to an input of the effective temperature profile control device (87) and which can be arranged in the body adjacent to the electrode (32, 33, 62, 63) or the electrode carrier (31, 61a-c).

10. An electrosurgery apparatus as set forth in claim 9 characterised in that the temperature sensor (86) is connected to an input of the calculation unit (87.2) and that the calculation unit (87.2) has means for verification or correction of a simulated, time-dependent effective temperature profile on the basis of the measurement signal of the temperature sensor.

11. An electrosurgery apparatus as set forth in one of the preceding claims characterised in that the effective temperature profile control device has means (87.1, 87.2, 87.6) for storing and calling up the time-dependency of control signals and for outputting control signals in accordance with a stored time-dependency.

12. An electrosurgery apparatus as set forth in one of the preceding claims characterised in that the electrode carrier (31, 61a-c) has a tubular element (61a, 61b) of electrically insulating material with a decreasing, in particular conical distal end, on the peripheral surface of which is arranged the electrode (62, 63) and in the interior of which is arranged the temperature control device (64, 65).

13. An electrosurgery apparatus as set forth in one of the preceding claims characterised by two electrodes (32, 33; 62, 63) on the electrode carrier (31; 61a, 61b).

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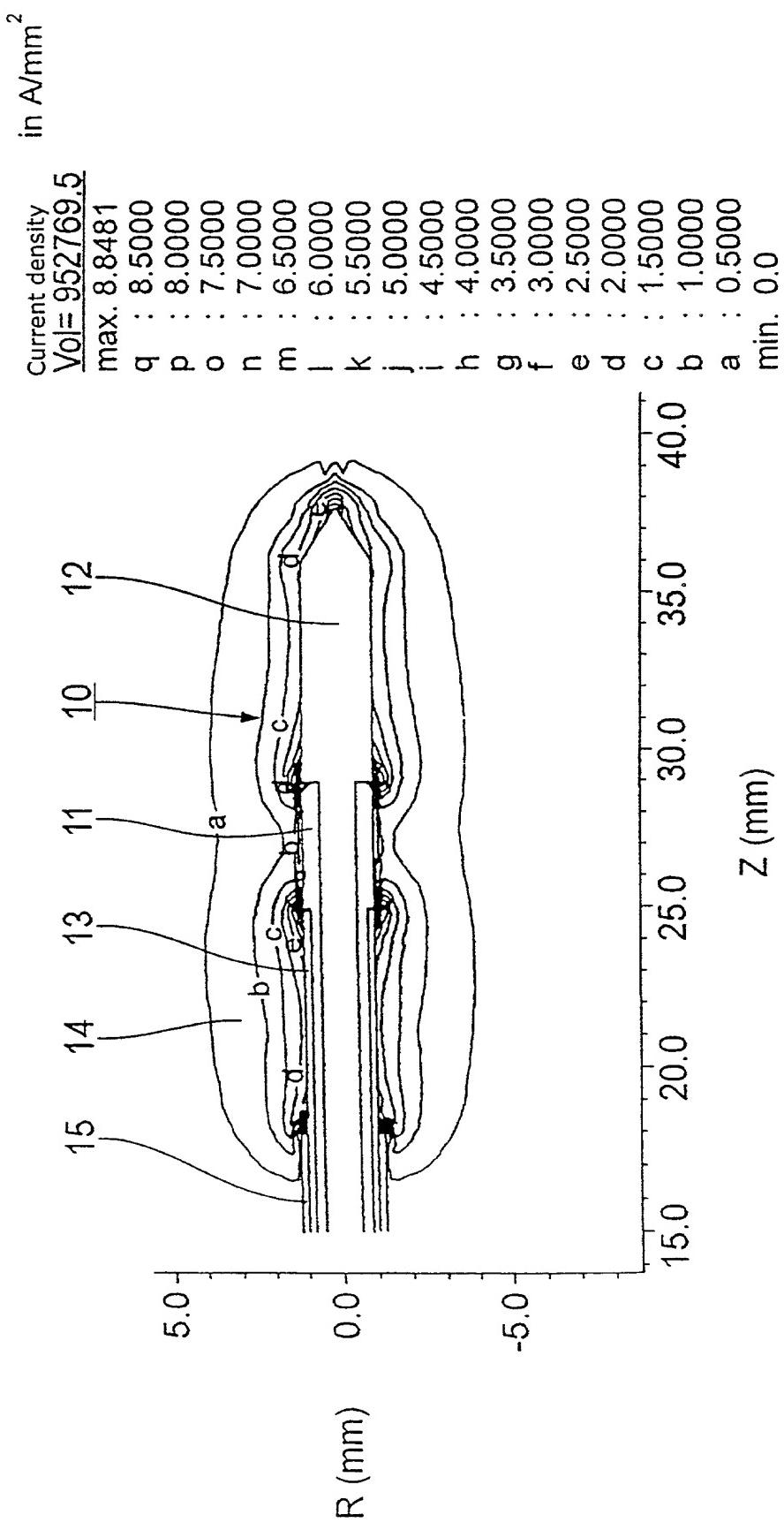


Fig. 1

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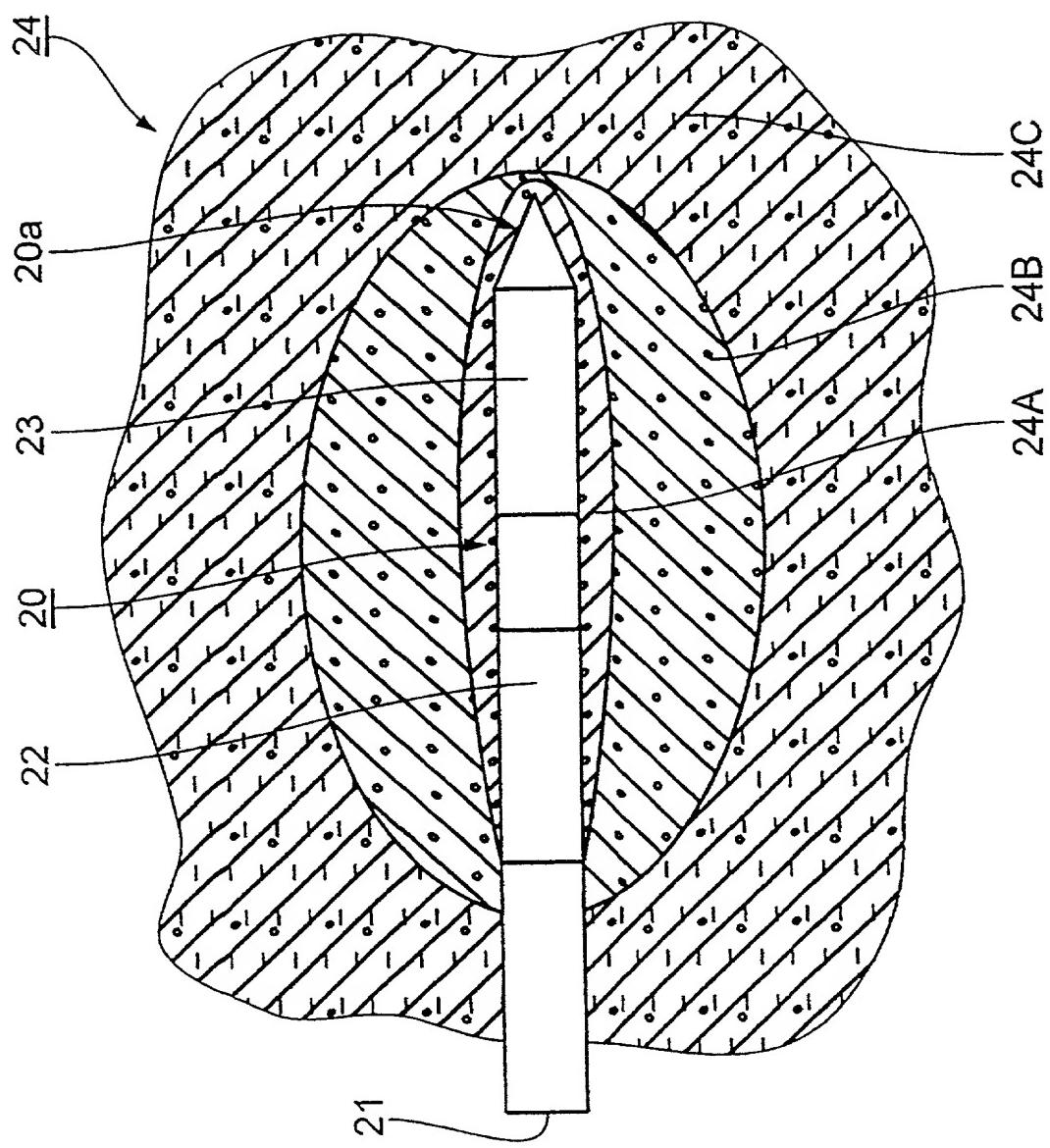


Fig.2

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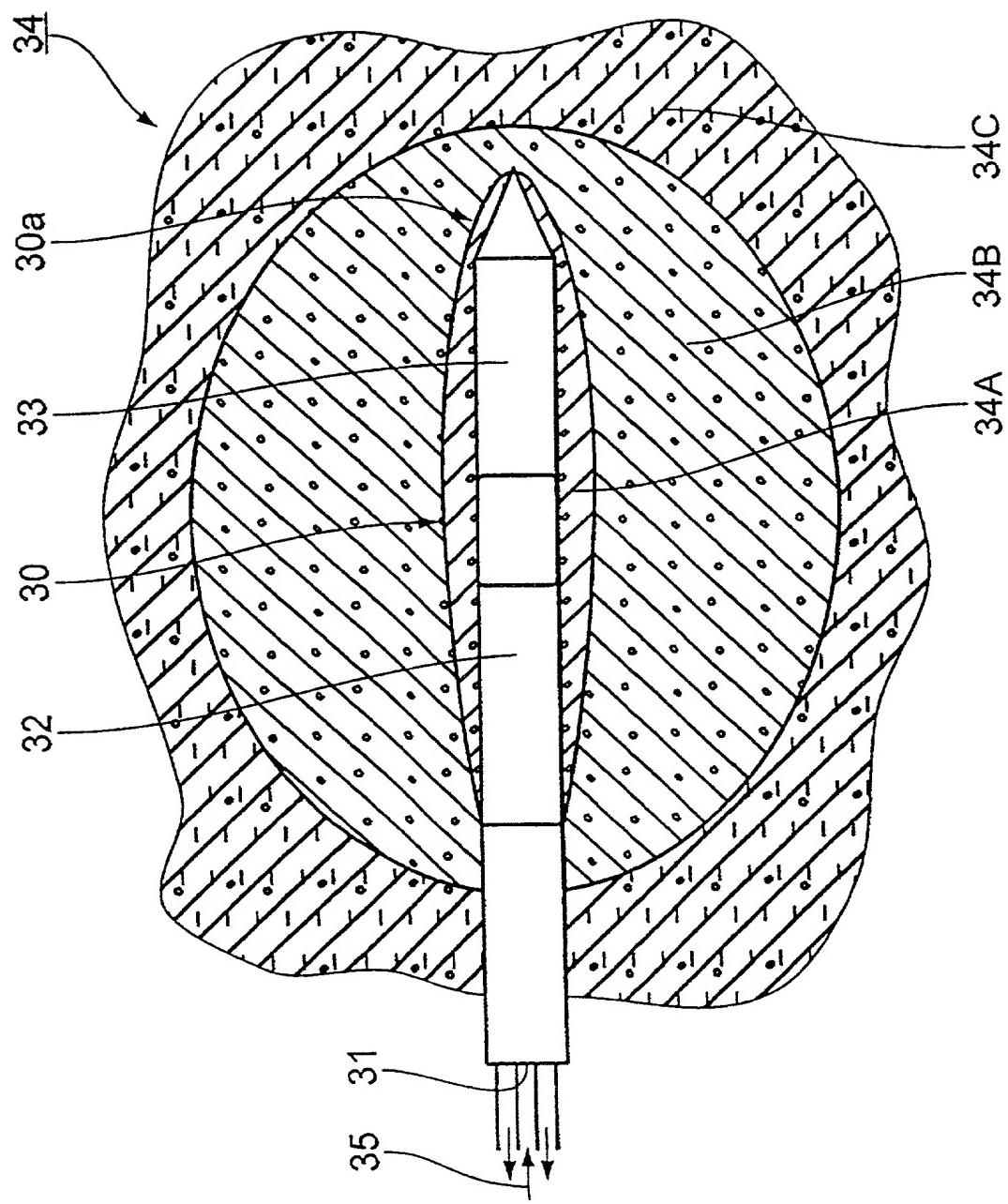


Fig. 3

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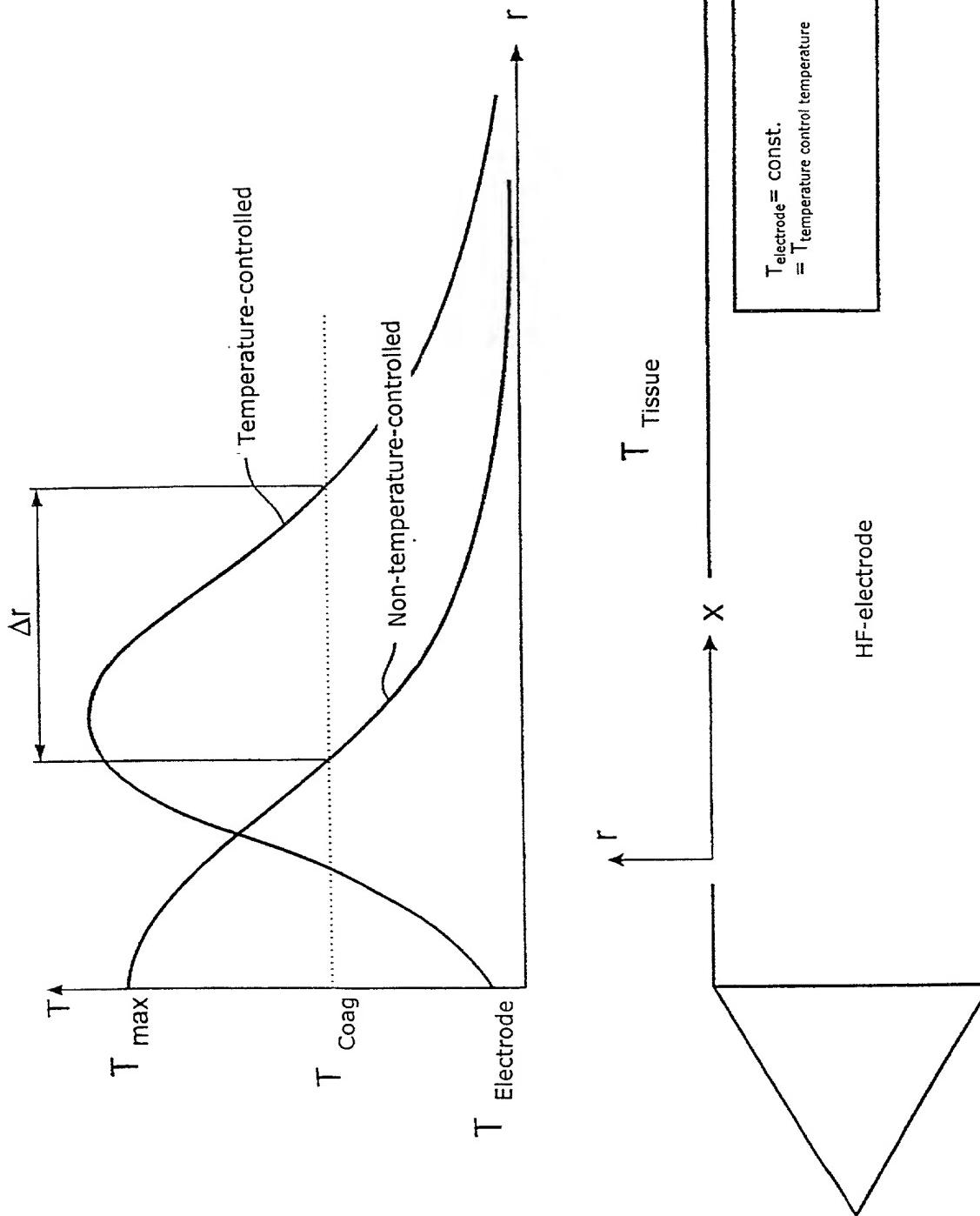


Fig.4

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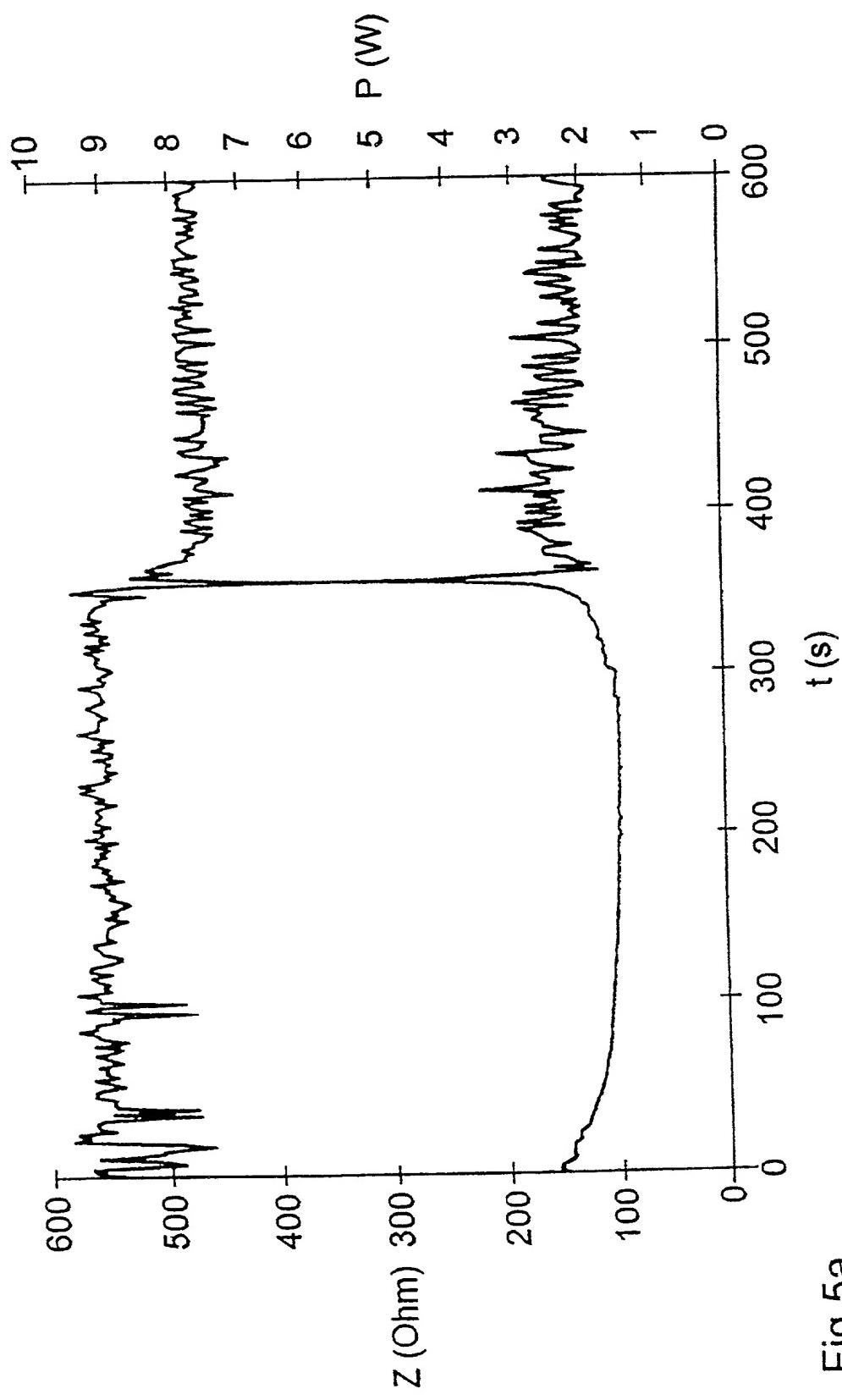


Fig.5a

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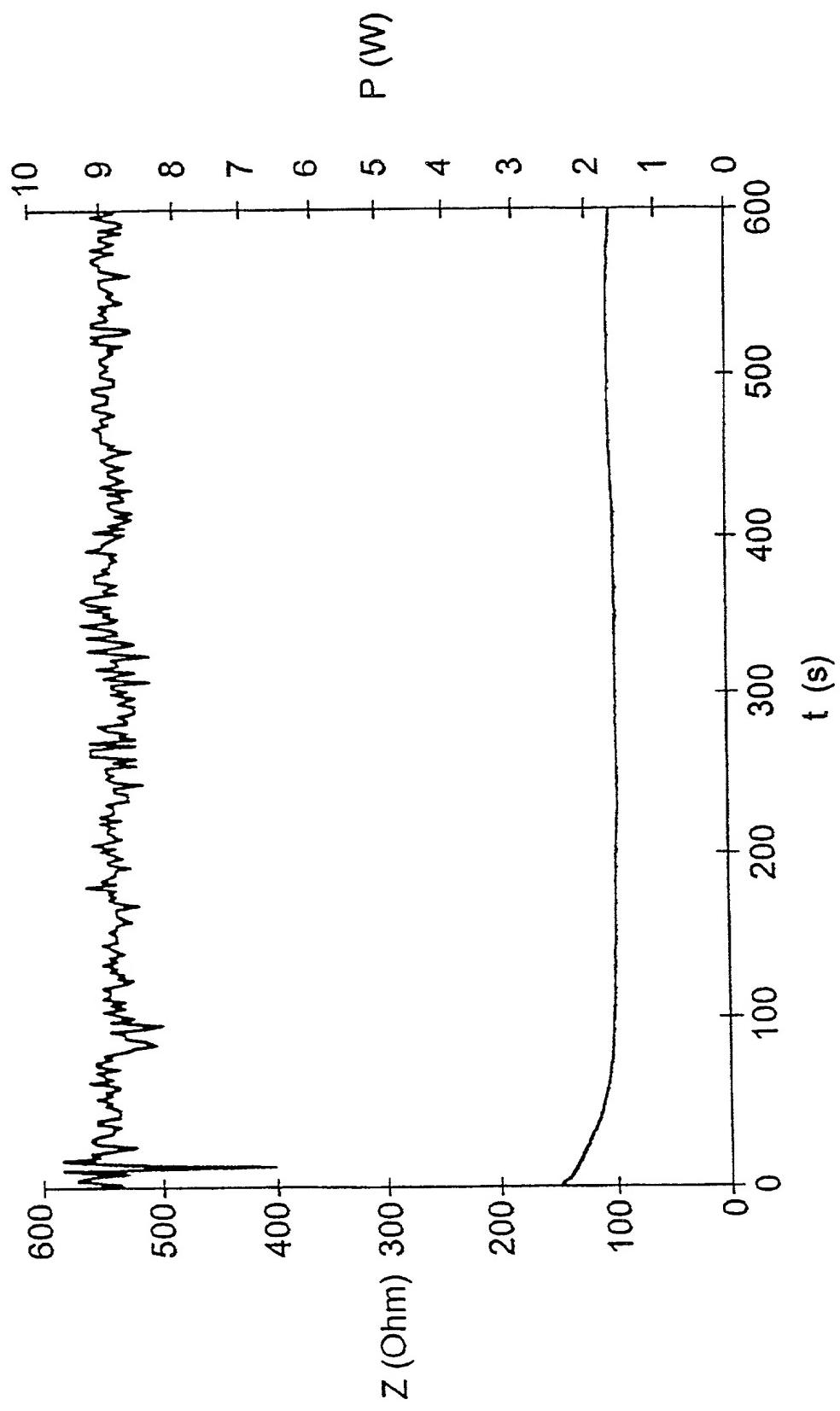


Fig.5b

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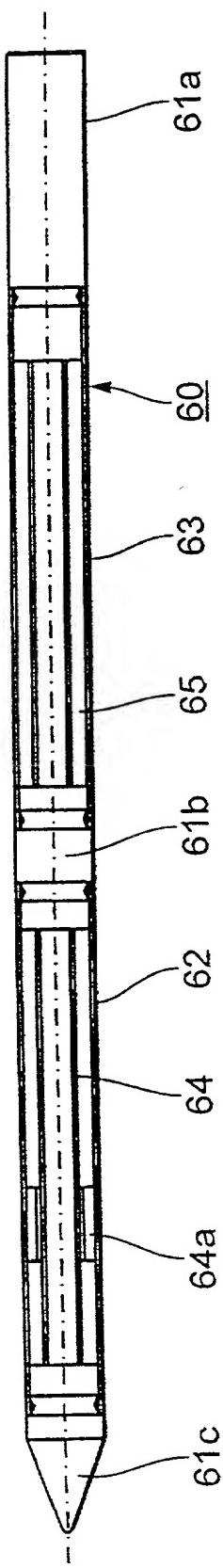


Fig.6a

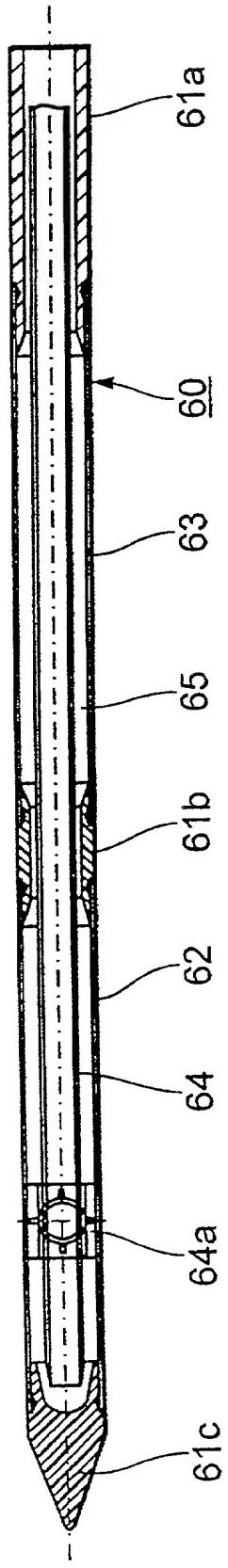


Fig.6b

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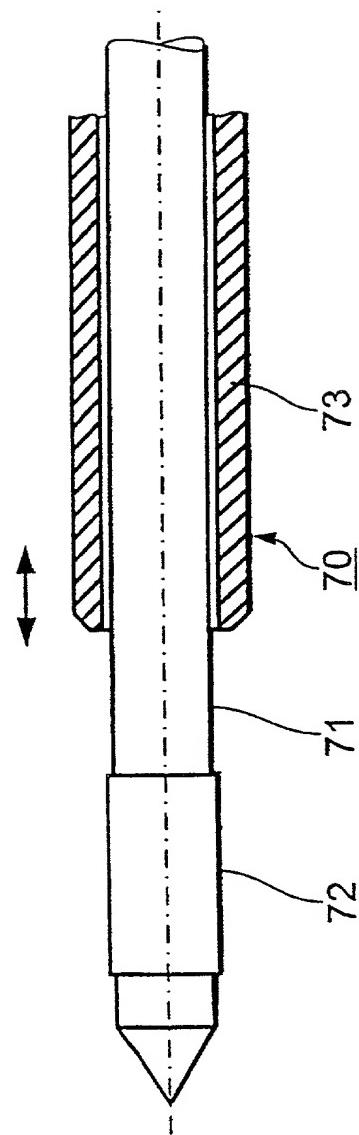


Fig. 7

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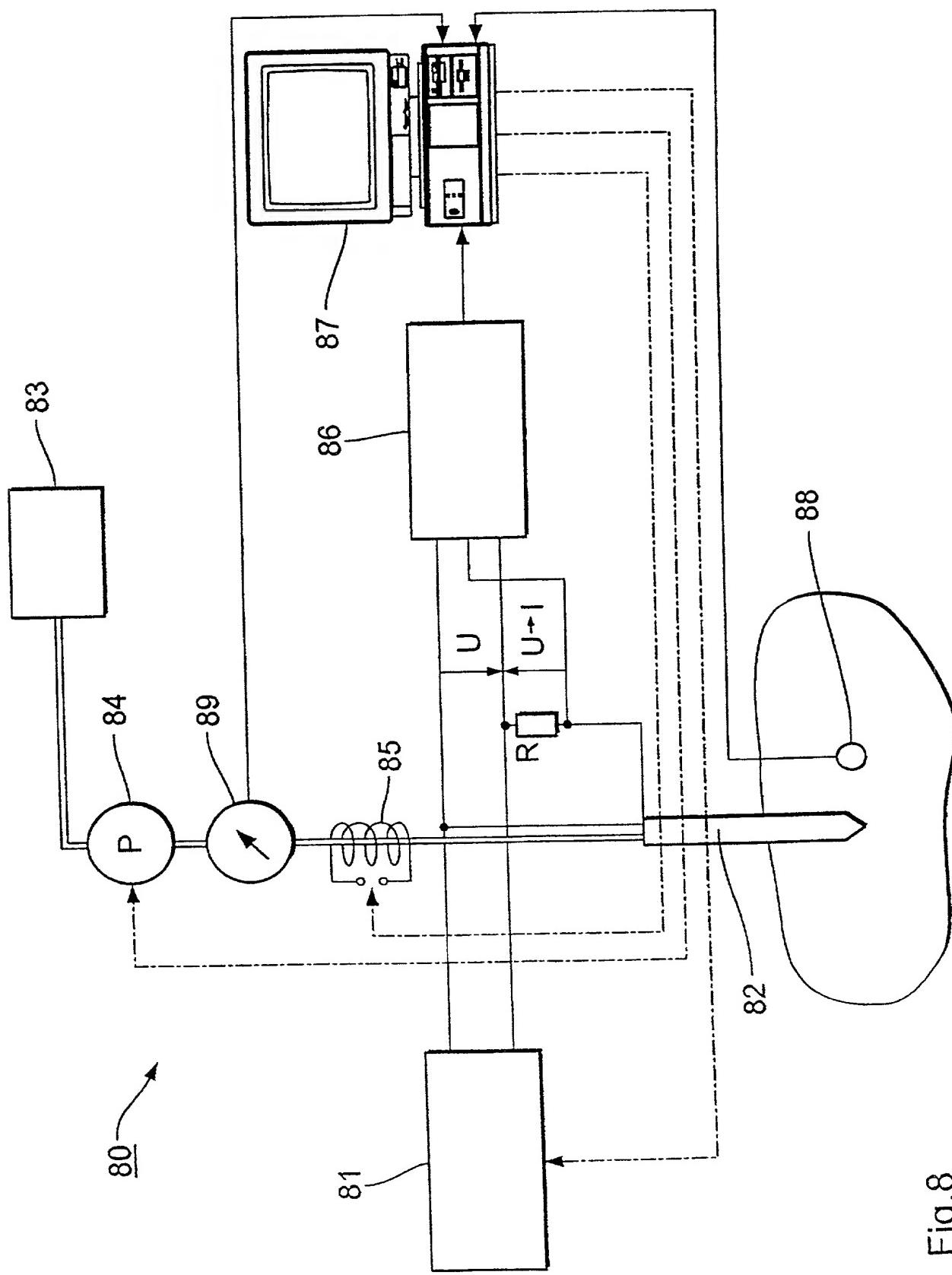


Fig.8

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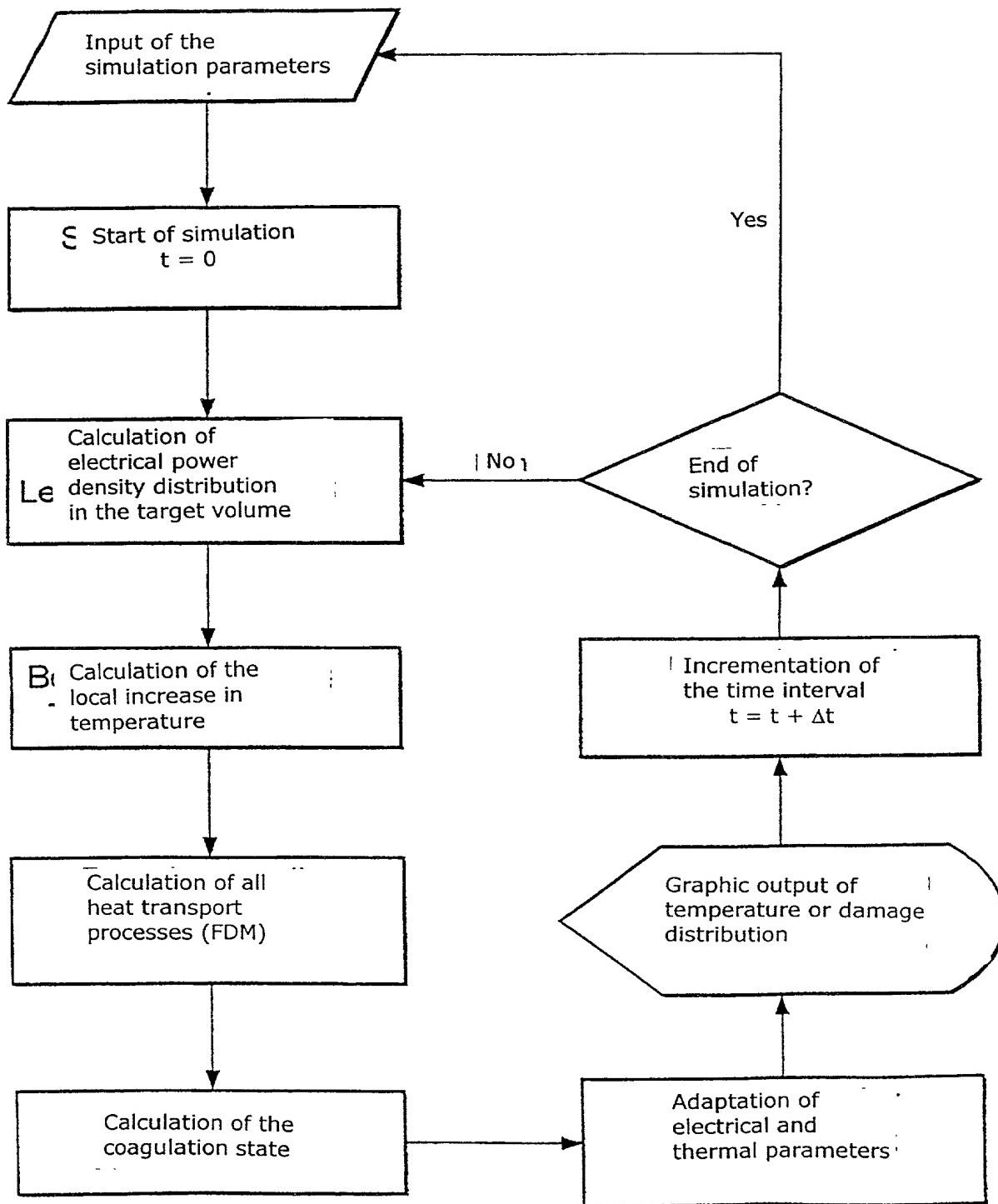


Fig.9

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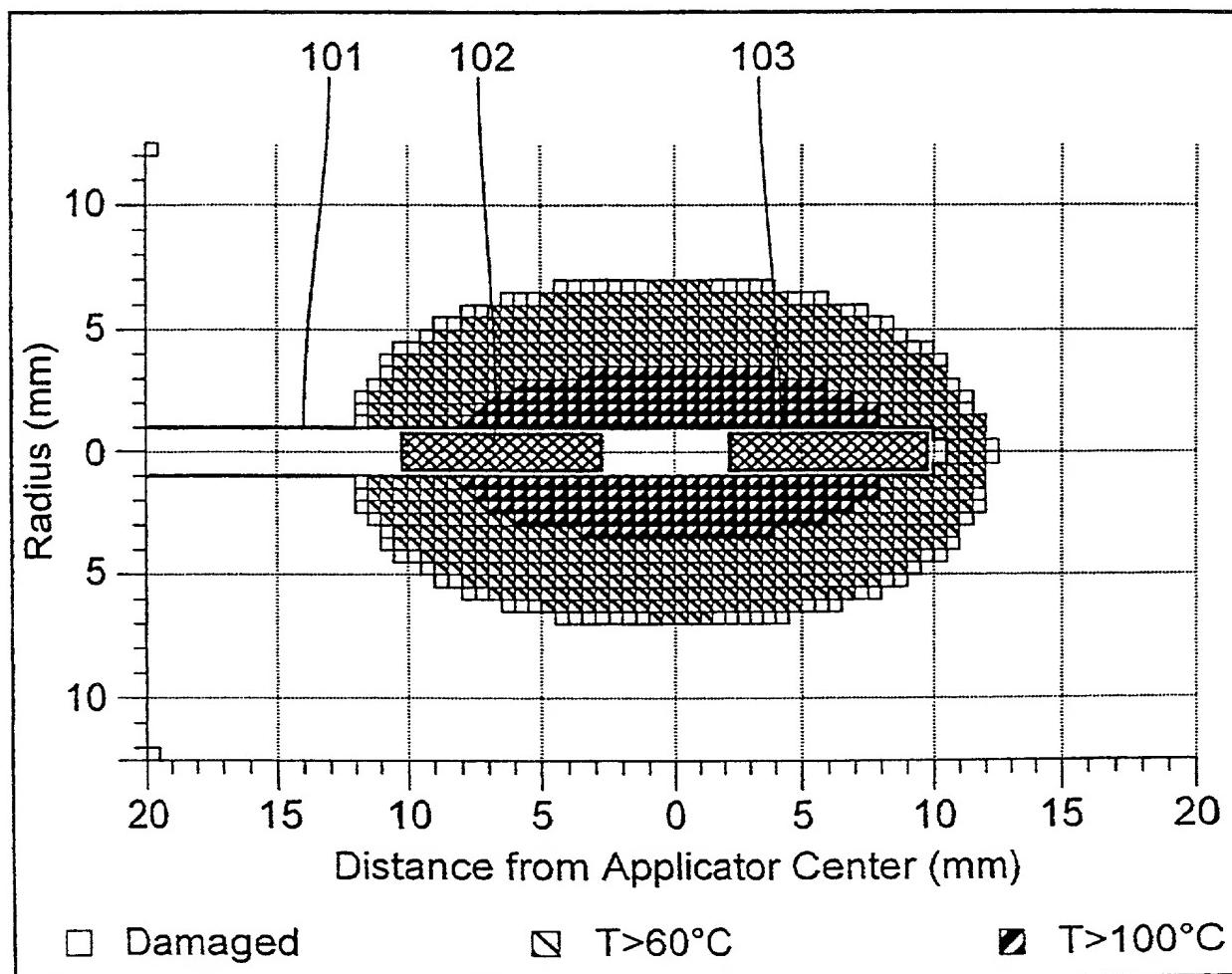


Fig.10

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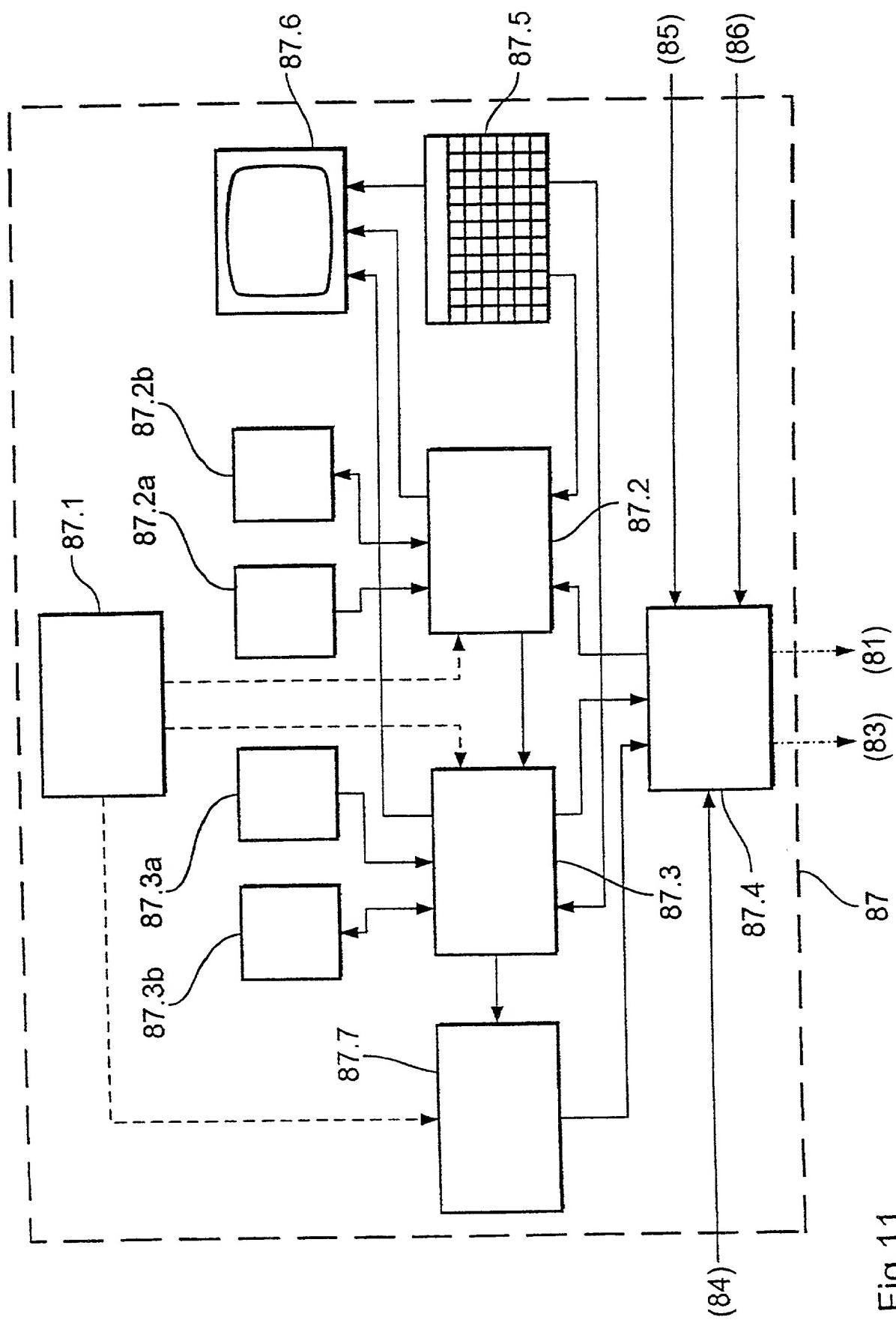


Fig. 11

**DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATIONS**

PATENT

Doctci No. 37167/DBP/B43

As I below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **ELECTROTHERMAL ARRANGEMENT FOR ELECTROTHERMAL TREATMENT OF HUMAN OR ANIMAL BOIMES**, the specification of which is attached hereto unless the following is checked:

was filed on 04 September 1997 as United States Application Number or PCT International Application Number PCT/US98/02693 and was amended on 19 August 1999 (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of the foreign application(s) for patent or inventor's certificate, or § 365(a) of my PCT International application which designated at least two countries other than the United States, listed below and have also identified below, any foreign application for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

<u>Application Number</u>	<u>Country</u>	<u>Filing Date (day/month/year)</u>	<u>Priority Claimed</u>
197 39 699.2	Germany	04 September 1997	Yes

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below.

<u>Application Number</u>	<u>Filing Date</u>
---------------------------	--------------------

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR § 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application.

<u>Application Number</u>	<u>Filing Date</u>	<u>Pending/Pending/Abandoned</u>
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POWER OF ATTORNEY: I hereby appoint the following attorneys and agents of the law firm CHRISTIE, PARKER & HALE, LLP to prosecute this application and any international application under the Patent Cooperation Treaty based on it and to transact all business in the U.S. Patent and Trademark Office connected with either of them in accordance with instructions from the assignee of the entire interest in this application; or from the first or sole inventor named below in the event the application is not assigned; or from BRENTUHR, SPEISER & PARTNER in the event the power granted herein is for an application filed on behalf of a foreign attorney or agent.

R. W. Johnston	(17,968	Wesley W. Monroe	(19,778	Patrick Y. Ikahara	(42,611
D. Bruce Proulx	(20,938	John W. Eldridge	(37,613	Mark Garcia	(31,913
Kayden A. Carney	(21,653	Gregory S. Lampert	(33,581	Gary J. Nelson	(44,217
Richard J. Ward, Jr.	(24,187	Grant T. Langton	(39,739	Raymond R. Tabanuelis	(43,915
Russell R. Palmer, Jr.	(22,994	Constantine Martineau	(39,759	Phuong-Quan Hoang	(41,819
Jeffrey T. Rahn	(20,396	Marilyn R. Khorandi	(P-	Kathy Mojibi	(41,419
Richard D. Schibol	(22,134		43,744)	Cynthia A. Denzer	(44,518

**DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATIONS**

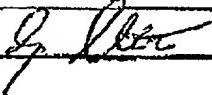
Docket No. 37187/DEP/243

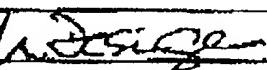
Walter G. Maxwell	(25,355	Daniel R. Kimball	(34,849	Jun-Young E. Jeon	(43,613
William P. Christie	(29,371	Craig A. Gelfound	(41,072	Marc A. Kartash	(44,8 0
David A. Dillard	(30,831	Syed A. Hasan	(41,097	John F. O'Rourke	(38,913
Thomas J. Daly	(32,213	Kathleen M. Olster	(42,092	Richard J. Pachulski	(28,218
Vincent G. Gioia	(19,939	Daniel M. Cavanagh	(41,661	Josephine E. Chang	(P-46,013
Edward R. Schwartz	(31,135	Molly A. Holman	(40,922	Albert J. Harris, Jr.	(P-46,113
John D. Carpenter	(34,133	Lucinda G. Audello	(42,270	Steven E. Johnson	(P-45,2 6
David A. Flumley	(37,298	Norman E. Carter	(30,453	Frank L. Cire	(42,4 9
		Juel A. Keith	(41,886		

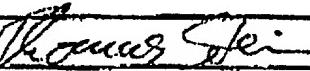
The authority under this Power of Attorney of each person named above shall automatically terminate and be revoked upon such person ceasing to be a member or associate of or of counsel to that law firm.

DIRECT TELEPHONE CALLS TO : D. Bruce Prout, 626733-9900
SEND CORRESPONDENCE TO : CHRISTIE, PARKER & HALE, LLP
 P.O. Box 7068, Pasadena, CA 91109-7068

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first joint inventor Gerhard Müller	Inventor's signature 	Date 01.03.2000
Residence and Post Office Address Ander Rehwiese 8, D-14129 Berlin, Germany		Citizenship German

Full name of second joint inventor Kai Deisinger	Inventor's signature 	Date 29.3.2000
Residence and Post Office Address Rubenstrasse 108, D-12157, Berlin, Germany		Citizenship German

Full name of third joint inventor Thomas Stein	Inventor's signature 	Date 01.03.2000
Residence and Post Office Address Kurfürstenstrasse 81, D-10787, Germany		Citizenship German

NCPAD/0101.14-22900 113 03/03